

Express Mail Label No. EV 246880765 US
Attorney Docket No. 6296.204-US
Serial No. 09/853,193; Filed: May 11, 2001

REMARKS/ARGUMENTS

This Amendment is submitted with an accompanying RCE and Information Disclosure Statement and claims 1, 4, 7-14, 21-29 and 32-85 are pending following entry of the present Amendment. **Applicant respectfully requests that the Amendment After Final filed on November 24, 2004 not be entered and that only this Amendment be entered.**

In addition Applicant directs the Examiner's attention to co-pending application 10/359,324.

The amendments to the claims presented herein, and added claims 32-85, find support in the Examples and at page 3, lines 20-21 and page 7, lines 4-26 of the specification.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH

In the May 26, 2004 Office Action, the Examiner rejected claims 1, 4-14 and 22-31 under section 112, first paragraph. In setting forth this rejection, the Examiner stated:

"the specification, while being enabling for a method for treating a critically ill patient or a critically ill polyneuropathy (CIPNP) patient comprising administering an amount of insulin as a blood glucose regulator effective to maintain blood glucose level in the patient in the range of about 60 mg/dL to about 130 mg/dL, or a method of treating a CIPNP patient comprising administering an amount of insulin as a blood glucose regulator effective to reduce the incidence of CIPNP and lengthen the time free of CIPNP in patients, does not reasonably provide enablement... where structure of the blood glucose regulator is not defined". (pages 3-4 of present Office Action).

While Applicant disagrees with the rejection and reserves the right to pursue the subject matter deleted from the claims in a continuation application, Applicant has, in the interests of advancing prosecution, limited the "blood glucose regulators" in the claimed methods to insulin, an insulin analogue, an active derivative of insulin or an insulin analogue, or a physiologically acceptable salt of said derivative. Thus, Applicant has limited the claimed methods to structurally defined blood glucose regulators (see page 7, lines 4-24 of the application) and accordingly, withdrawal of this rejection is respectfully requested.

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REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, SECOND PARAGRAPH

In the May 26, 2004 Office Action, the Examiner rejected claims 4-14 as being indefinite for lacking an essential step in the method of treating a patient suffering from CIPNP; namely the outcome of such treatment. In particular, the Examiner alleges that “to treat CIPNP” does not indicate the effect of administering a glucose regulator in the treatment, eg., reducing the incidence of CIPNP and lengthening the time free of CIPNP in patients.

In reply, Applicant respectfully traverses this rejection.

Whether a claim is indefinite depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification. Here, Applicant submits that those of skill in the art reading the claim in light of the present application would clearly understand whether a patient with CIPNP had been treated by the claimed method. Indeed, the Examiner notes that the application discloses that treatment of a CIPNP patient may be measured by criteria such as the reduction in the incidence of CIPNP and the lengthening of time free from CIPNP. Accordingly, Applicant submits that the phrase “to treat CIPNP” would have a clear and definite meaning to one skilled in the art and withdrawal of the section 112, second paragraph rejection is therefore respectfully requested.

In the Advisory Action dated December 17, 2004, the Examiner indicated that claims 33, 34, 36, 41, 42, 44, 48, 49, 51, 56, 57 and 59 presented in the November 24, 2004 Amendment After Final would be rejected as indefinite because it is not clear what sequence is referred to by the recitation of specific analogs such as AspB28 in claim 33 without the provision of a sequence listing. As claims 33, 34, 36, 41, 42, 44, 48, 49, 51, 56, 57 and 59 presented in this Amendment are identical to those claims presented in the not-entered November 24, 2004 Amendment After Final, Applicant wishes to address this rejection as it might be applied against the present claims.

In particular, Applicant submits that the plain language of added claims 33, 34, 36, 41, 42, 44, 48, 49, 51, 56, 57 and 59 is clear. The reference in these claims to AspB28 human insulin, LysB28, ProB29 human insulin and des-Thr 30 human insulin would have a clear and definite meaning to those of skill in the art; namely, AspB28 human insulin means

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the amino acid sequence of human insulin except that the amino acid at position B28 is Asp, LysB28, ProB29 human insulin means the amino acid sequence of human insulin except that the amino acid at position B28 is Lys and the amino acid at position B29 is Pro, and des-ThrB30 human insulin means the amino acid sequence of human insulin except that the amino acid normally present at position B30 of human insulin (Thr) is deleted. Both the amino acid sequence of human insulin and the aforementioned designations were known by those skilled in the art well prior to the May 5, 2000 priority filing date of the present application. Evidence that the terms AspB28 human insulin, LysB28, ProB29 human insulin and des-ThrB30 human insulin are well known in the art and are accepted by the USPTO without the provision of a Sequence Listing is provided by US patents which claim benefit to a filing date earlier than that of the present application [see, for example, the claims of US patents 6,551,992 (see also col.5, lines 19-21), RE37,971 (see also col.3, lines 38-39), and 6,335,316, copies attached herewith]. Accordingly, Applicant submits that the language of added claims 33, 34, 36, 41, 42, 44, 48, 49, 51, 56, 57 and 59 presented herewith fully complies with the requirements of 35 USC 112, second paragraph.

In view of the above amendments and remarks, Applicant respectfully submits that the present application is in condition for allowance.

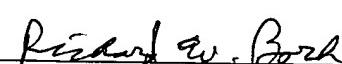
The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Please charge any deficiencies or overpayment to Deposit Account No.

14-1447.

Respectfully submitted,

Date: January 24, 2005


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